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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,433	07/29/2003	Glenn C. Rice	9511-102-27 CONT	5292

7590 01/12/2006

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EXAMINER	
SANG, HONG	
ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 01/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/628,433	RICE ET AL.	
	Examiner	Art Unit	
	Hong Sang	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 July 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *13-24* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

RE: Rice et al.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 17, drawn to a fibrocyte-based therapeutic formulation of claim 13, wherein the antigenic component is viral, classified in class 530, subclass 300, for example.

   II. Claims 18, drawn to a fibrocyte-based therapeutic formulation of claim 13, wherein the antigenic component is bacterial, classified in class 530, subclass 300, for example.

   III. Claims 19, drawn to a fibrocyte-based therapeutic formulation of claim 13, wherein the antigenic component is fungal, classified in class 530, subclass 300, for example.

   IV. Claims 20, drawn to a fibrocyte-based therapeutic formulation of claim 13, wherein the antigenic component is parasite, classified in class 530, subclass 300, for example.

   V. Claims 21, drawn to a method for establishing an immune response according to claim 15, wherein the antigenic component is viral, classified in class 424, subclass 186.1.

   VI. Claims 22, drawn to a method for establishing an immune response according to claim 15, wherein the antigenic component is bacterial, classified in class 424, subclass 190.1.

VII. Claims 23, drawn to a method for establishing an immune response according to claim 15, wherein the antigenic component is fungal, classified in class 424, subclass 275.2.

VIII. Claims 24, drawn to a method for establishing an immune response according to claim 15, wherein the antigenic component is parasite, classified in class 424, subclass 191.1.

2. Claims 13, 14, 15 and 16 are linking claims. Claims 13 and 14 link groups I-IV together. Claims 15 and 16 links groups V-VIII together. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP j 804.01.

3. The inventions are distinct, each from the other because of the following reasons: Inventions I-IV are patentably distinct products.

The inventions of groups I-IV are patentably distinct because the formulations claimed in each of the different groups are composed of different components and are derived from a different source materials. For group I, the antigenic component is derived from virus, for group II, it is derived from bacteria, for group III, it is derived from fungi, and for group IV, it is derived from parasite. The antigenic components derived from different sources have different structures and different functions. The immune responses induced by these different antigenic components are different. Moreover, distinct structures and functions require separate searches. For example, the search for peptides derived from a bacteria may not overlap with a search for viral peptides or peptides derived from a virus. As such, it would be burdensome to search the inventions of groups I-IV together.

Inventions V-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. The methods of groups V-VIII are unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using a structurally and functionally divergent material or comprises different methodological steps. Groups V-VIII differ from each other in that the material used in these methods is different. For group V, a viral-based antigenic component is used, for group VI, a bacterial-based antigenic

component is used, for group VII, a fungal-based antigenic component is used, and for group VIII, a parasitic-based antigenic component is used. Therefore, each method is divergent in materials and steps. For these reasons the Inventions V-VIII are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. As such, it would be burdensome to search the inventions of groups V-VIII together.

Inventions I-IV and V-VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the immune response can be established by using purified tumor antigen as opposed to being established by using a fibrocyte-based vaccine formulation.

Searching the inventions of groups I-IV and V-VIII together would impose serious search burden. The inventions of groups I-IV and V-VIII have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for vaccine formulation and the method of establishing an immune response using a vaccine formulation are not coextensive. The search for groups V-VIII would require a text search for the method of establishing an immune response in addition to a search

for the vaccine formulation. Prior art which teaches a vaccine formulation would not necessarily be applicable to the method of using the vaccine formulation. Moreover, even if the vaccine formulation was known, the method of using the product may be novel and unobvious in view of the preamble or active steps.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. This application contains claims directed to the following patentably distinct species of the claimed invention:

(i) pulsed antigen protein, peptide, lipid, carbohydrate, synthetic antigen of protein, synthetic antigen of peptide, synthetic antigen of lipid, synthetic antigen of carbohydrate, gene expressing specific non-tumor protein, gene expressing specific non-tumor peptide, non-tumor cells and non-tumor cell membrane fragments.

The above listed antigenic components i.e. protein, peptides, lipid, carbohydrate, synthetic antigen, gene, cells, cell membrane fragments are all structurally and functionally distinct.

(ii) pulsing fibrocytes in culture with a non-tumor antigen peptide,

pulsing fibrocytes in culture with a non-tumor antigen protein,

transfecting fibrocytes with a gene encoding a specific non-tumor antigenic peptide, transfecting fibrocytes with a gene encoding a specific non-tumor antigenic

protein, fusing non-tumor cells with fibrocytes, fusing non-tumor cell membrane fragments with fibrocytes.

Each of the method uses structurally and functionally distinct products, for example, a protein, a gene, a fibrocyte. Therefore, they are patentably distinct.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re

Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hong Sang whose telephone number is (571) 272 8145. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hong Sang
Art Unit 1643
Jan. 5, 2006

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER